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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/691,763	10/18/00	VERTINO	P E0355/7003/E

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EXAMINER	
GOLDBERG, J	
ART UNIT	PAPER NUMBER
1655	13

DATE MAILED: 06/20/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/691,763	VERTINO, PAULA M.	
	Examiner	Art Unit	
	Jeanine A Enewold Goldberg	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

P riod for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 April 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5,13,15,18,21,22,30,38,47,58,61,67,68,71,72,89,95,101 and 105* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims *1,5,13,15,18,21,22,30,38,47,58,61,67,68,71,72,89,95,101 and 105* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

DETAILED ACTION

1. Claims 1, 5, 13, 15, 18, 21, 22, 30, 38, 47, 58, 61, 67, 68, 71, 72, 89, 95, 101 are currently pending and subject to restriction.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 47, drawn to a method for identifying a subject at risk of developing a tumor by determining an increase in the level of methylation of the CpG island containing TMS1 nucleic acid molecules and a method for identifying a subject having cancer who is at risk of being non-responsive to an anti-cancer therapy using a nucleic acid assay, classified in class 435, subclass 6.

II. Claim 5, drawn to a method for determining a risk of developing a disorder characterized by abnormal methylation of a CpG island by measuring expression, classified in class 435, subclass 7.1.

III. Claims 13, 15, 18, 30, 58, drawn to a method for treating a subject at risk of developing a disorder by administering a demethylating agent, classified in class 424, subclass 9.2, for example.

IV. Claims 21-22, 38, 61, 67, drawn to a method for treating a subject having or at risk of developing a disorder characterized by abnormal methylation of a CpG isalnd containing TMS1 nucleic acid molecule by administering a

CAFD containing molecule to a subject, classified in class 514, subclass 44, 2, for example.

V. Claims 68, 71, 72, drawn to nucleic acids, classified in class 536, subclass 23.1, for example.

VI. Claims 89, drawn to a composition comprising an agent which binds to a polypeptide, classified in class 424, subclass 130.1, for example.

VII. Claim 95, drawn to a method for identifying a nucleic acid molecule transcriptionally down-regulated following methylation by overexpressing a methyltransferase molecule and identifying a differentially expressed molecule which has a lower level of expression in the experimental cell, classified in class 435, subclass 7.1.

VIII. Claims 101 and 105, drawn to a method for identifying a TMS1 polypeptide binding partner by comparing the binding assay results, classified in class 424, subclass 9.2, for example.

3. The inventions are distinct, each from the other because of the following reasons:

A) The inventions of Groups I, II, III, IV, VII, VIII are patentably distinct methods because they each have different objectives, different uses, different reagents and different method steps. The method of Group I.is for method for identifying a subject at risk of developing a tumor by determining an increase in the level of methylation of the CpG island containing TMS1 nucleic acid molecules and a method for identifying a subject having cancer who is at risk of being non-responsive to an anti-cancer therapy

using a nucleic acid assay. The method of Group II is for a method for determining a risk of developing a disorder characterized by abnormal methylation of a CpG island by measuring expression. The method of Group III is for a method for treating a subject at risk of developing a disorder by administering a demethylating agent. The method of Group IV is for a method for treating a subject having or at risk of developing a disorder characterized by abnormal methylation of a CpG isalnd containing TMS1 nucleic acid molecule by administering a CAFD containing molecule to a subject. The method of Group VII is for a method for identifying a nucleic acid molecule transcriptionally down-regulated following methylation by overexpressing a methyltransferase molecule and identifying a differentially expressed molecule which has a lower level of expression in the experimental cell. Finally, the method of Group VIII is for a method for identifying a TMS1 polypeptide binding partner by comparing the binding assay results. Thus each of these methods have different objectives. Further each of these methods use different reagents. For example the method of Group I, III and VII rely on the nucleic acid. Methods of Groups VIII rely upon the polypeptide. Therefore the methods are distinct over one another.

B) The inventions of Groups V and VI are patentably distinct products because the DNA of Group I and the composition that binds selectively to a polypeptide have different structures, properties and functions. The DNA of Group I is composed of nucleotides linked in phospodiester bonds and arranged in space as a double helix. The DNA can function not only for the expression of the protein but also as a probe in a nucleic acid hybridization assay and in a nucleic acid amplification assay, for example.

The composition which binds to the polypeptide encompasses peptides, antibodies. In contrast, the polypeptide of Group II is composed of amino acids linked in peptide bonds and arranged spatially in a number of different tertiary structures including alpha helices, beta-pleated sheets, and hydrophobic loops (transmembrane domain). The polypeptide can function not only as a receptor but also for the generation of polyclonal and monoclonal antibodies and for the affinity purification of those antibodies or of ligands for the receptor. In the case that the binding agent is an antibody, the antibody of Group III is composed of amino acids linked in peptide bonds and arranged spatially in a very specific tertiary structure that allows that antibody to specifically bind to particular regions, i.e. epitopes, of the encoded polypeptide. The antibody can function for the detection and purification of the polypeptide to which it binds. Therefore these inventions are novel and unobvious over one another.

C) Group V and Groups (II, IV, VI, VIII) are patentable distinct inventions because the nucleic acid of Group V is not relied upon in the method of Groups II, IV, VI, VIII. Instead Groups II, IV, VI, VIII uses a polypeptide. Therefore, the inventions are novel and unobvious over one another.

D) Group VI and Groups (I, II, III, V, VII) are patentable distinct inventions because the nucleic acid of Group VI is not relied upon in the method of Groups I, II, III, V, VII. Instead Group I, II, III, V, VII uses nucleic acids. Therefore, the inventions are novel and unobvious over one another.

E) Inventions V and Inventions (I, II, III, V, VII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the

following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid of Group V can be used in hybridization assays to identify the gene, in purification methods, aptamer screening methods, and antisense methods.

F) Inventions VI and Inventions (II, IV, VI, VIII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides may be used to raise antibodies. Further the antibodies may be used to antibody can function for the detection and purification of the polypeptide to which it binds.

4. A telephone call was made to Edward Gates on May 16, 2001 to request an oral election to the above restriction requirement, but did not result in an election being made.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Enewold Goldberg whose telephone number is (703) 306-5817. The examiner can normally be reached Monday-Thursday from 7:00AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax number for this Group is (703) 305- 3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jeanine Enewold Goldberg
June 19, 2001 JEG

LISA B. ARTHUR
PRIMARY EXAMINER
GROUP ~~1800~~ 1600